

QUALITY SYSTEM

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# EC-CERTIFICATE

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Directive 93/42/EEC

Manufacturer: Medikro Oy  
Pioneerinkatu 3  
FI-70800 Kuopio  
Finland

Coverage of Certificate: Design, manufacture and final inspection

Product category: Spirometers and their accessories

Valid until: 30<sup>th</sup> October 2020

The manufacturer's quality system for the design, manufacture and final inspection of the aforesaid product category has been evaluated and meets the provisions of Council Directive 93/42/EEC as set out in Annex II Section 3. This approval is valid until the expiry date provided that the manufacturer fulfils the obligations imposed by Annex II in Directive 93/42/EEC. Products covered by the certificate are specified in the attachment(s).

Tampere, 30<sup>th</sup> October 2015



Aliisa Siljander

Certificate no.

**VTT-C-11451-01-1056-566-15**



Tuomas Toivonen

Notified Body no. 0537:  
VTT Expert Services Ltd.  
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FINLAND  
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**Attachment 1 to the Certificate number: VTT-C-11451-01-1056-566-15**

<b>Manufacturer:</b>	Medikro Oy Pioneerinkatu 3, FI-70800 Kuopio Finland		
<b>Activity and product category:</b>	Design, manufacture and final inspection of spirometers and their accessories		
<b>Products:</b>	The certificate covers the following products:		
	<i>Brand name</i>	<i>Model</i>	<i>Class</i>
	<b>Spirometers (GMDN-code: 13680)</b>		
	Medikro® Spirostar DX (Serial) Spirometer	M921	Ila
	Medikro® serial OEM Spirometer	M921-E	Ila
	D9-W-WA OEM Spirometer	M921-WA	Ila
	Medikro® Spirostar USB Spirometer	M929	Ila
	Medikro® USB OEM Spirometer	M929-E	Ila
	D9-W-WA USB OEM Spirometer (SpiroPerfect)	M929-WA	Ila
	Medikro® Nano	M913	Ila
	Medikro® Nano OEM	M913-E	Ila
	Medikro® Pro	M915	Ila
	Medikro® Pro OEM	M915-E	Ila
	410027 Spirometry Kit	M915-WA	Ila
	Medikro® Primo	M914	Ila
	Medikro® Primo OEM	M914-E	Ila
	<b>Software (GMDN-code: 13680)</b>		
	Medikro® Spirometry Software	M9831	Ila



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	<p><b>Transducer</b> (GMDN-code: 44545) SpiroSafe Disposable Flow Transducer</p> <p>M9228, M9242, M9242-WA, M9256, M9256-WA</p> <p style="text-align: right;">IIa</p>
<p><b>Date:</b></p>	<p>Tampere, 30<sup>th</sup> October, 2015</p> <p style="text-align: center;"></p> <p> Aliisa Siljander</p> <p> Tuomas Toivonen</p>

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